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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,112	05/25/2001	Philippe Benaroch	24190.0003	8305

7590

09/10/2002

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EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/10/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/831,112

Applicant(s)

BENAROCH ET AL.

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: ____.                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11, 32, 47 and 51, drawn to a membrane vesicle that comprises a recombinant MHC Class II molecule, and composition thereof.

Group II, claim(s) 1, 6-11, 32 and 51, drawn to a membrane vesicle that comprises a recombinant MHC Class I molecule, and composition thereof.

Group III, claim(s) 12-15 and 32, drawn to a membrane vesicle that is obtained from a mastocyte or mastocyte derived cell, comprising one or more heterologous molecules of interest, and composition thereof.

Group IV, claim(s) 16 and 32, drawn to a membrane vesicle that comprises a recombinant fusion molecule between a polypeptide of interest and a signal sequence, and composition thereof, .

Group V, claim(s) 17-20 and 49-50, drawn to an exosome-producing cell, comprising one or more recombinant nucleic acids coding for a major Histocompatibility complex.

Group VI, claim(s) 21-25, drawn to a method for producing an exosome containing a defined recombinant molecule comprising culturing a mastocyte or mastocyte derived cell.

Group VII, claim(s) 26-30, drawn to a method for preparing an exosome containing a peptide-MHC complex of defined composition.

Group VIII, claim(s) 31, drawn to a method for modifying the composition of an exosome.

Group IX, claim(s) 33-35 and 48, drawn to a method for producing antibodies using the vesicle of claim 1 of Group I.

Group X, claim(s) 33-35 and 48, drawn to a method for producing antibodies using the vesicle of claim 1 of Group II.

Art Unit: 1644

Group XI, claim(s) 33-35 and 48, drawn to a method for producing antibodies using the vesicle of claim 12 of Group III.

Group XII, claim(s) 33-35 and 48, drawn to a method for producing antibodies using the vesicle of claim 16 of Group IV.

Group XIII, claim(s) 36, drawn to a method for the detection of an antigen using an antibody of Group IX.

Group XIV, claim(s) 36, drawn to a method for the detection of an antigen using an antibody of Group X.

Group XV, claim(s) 36, drawn to a method for the detection of an antigen using an antibody of Group XI.

Group XVI, claim(s) 37, drawn to a method for the preparation of a therapeutic composition intended to inhibit the interaction between the receptor of a T-lymphocyte and the MHC-peptide complex for which it is specific, wherein said therapeutic composition comprises an antibody of claim 34, of Group IX.

Group XVII, claim(s) 37, drawn to a method for the preparation of a therapeutic composition intended to inhibit the interaction between the receptor of a T-lymphocyte and the MHC-peptide complex for which it is specific, wherein said therapeutic composition comprises an antibody of claim 34, of Group X.

Group XVIII, claim(s) 37, drawn to a method for the preparation of a therapeutic composition intended to inhibit the interaction between the receptor of a T-lymphocyte and the MHC-peptide complex for which it is specific, wherein said therapeutic composition comprises an antibody of claim 34, of Group XI.

Group XIX, claim(s) 37, drawn to a method for the preparation of a therapeutic composition intended to inhibit the interaction between the receptor of a T-lymphocyte and the MHC-peptide complex for which it is specific, wherein said therapeutic composition comprises a membrane vesicle that comprises a recombinant MHC Class II molecule, of Group I.

Group XX, claim(s) 37, drawn to a method for the preparation of a therapeutic composition intended to inhibit the interaction between the receptor of a T-lymphocyte and the MHC-peptide complex for which it is specific, wherein said therapeutic composition comprises a membrane vesicle that comprises a recombinant MHC Class I molecule, of Group II.

Group XXI, claim(s) 38 and 40-41, drawn to a method of using a membrane vesicle according to claim 1, Group I, for the detection of partners specific for a protein molecule in a biological sample.

Art Unit: 1644

Group XXII, claim(s) 38 and 40-41, drawn to a method of using a membrane vesicle according to claim 1, Group II, for the detection of partners specific for a protein molecule in a biological sample.

Group XXIII, claim(s) 38-41, drawn to a method of using a membrane vesicle according to claim 12, Group III, for the detection of partners specific for a protein molecule in a biological sample.

Group XXIV, claim(s) 38-41, drawn to a method of using a membrane vesicle according to claim 16, Group IV, for the detection of partners specific for a protein molecule in a biological sample.

Group XXV, claim(s) 42, drawn to a method for the detection of the presence of T-lymphocytes specific to antigen-MHC complexes in a biological sample, comprising placing said sample in contact with an exosome labeled according to claim 51, containing said antigen-MHC complex, and evidencing the labeling of T-lymphocytes in said sample.

Group XXVI, claim(s) 43, drawn to a method of using the vesicle of claim 7 of Group I for clonal amplification or ex vivo stimulation of T-lymphocytes, or both, wherein said T-lymphocytes are cytotoxic or auxiliary T-lymphocytes, or both.

Group XXVII, claim(s) 43, drawn to a method of using the vesicle of claim 7 of Group II for clonal amplification or ex vivo stimulation of T-lymphocytes, or both, wherein said T-lymphocytes are cytotoxic or auxiliary T-lymphocytes, or both.

Group XXVIII, claim(s) 44, drawn to a method of using a vesicle according to claim 1 of Group I for the preparation of a composition to deliver said molecule to a cell.

Group XXIX, claim(s) 44, drawn to a method of using a vesicle according to claim 1 of Group II for the preparation of a composition to deliver said molecule to a cell.

Group XXX, claim(s) 44, drawn to a method of using a vesicle according to claim 12 of Group III for the preparation of a composition to deliver said molecule to a cell.

Group XXXI, claim(s) 44, drawn to a method of using a vesicle according to claim 16 of Group IV for the preparation of a composition to deliver said molecule to a cell.

Group XXXII, claim(s) 45, drawn to a composition containing one or more exosomes immobilized on a support.

Group XXXIII, claim(s) 46, drawn to a method for the purification of cells using a membrane vesicle according to claim 1 of Group I.

Group XXXIV, claim(s) 46, drawn to a method for the purification of cells using a membrane vesicle according to claim 1 of Group II.

Art Unit: 1644

Group XXXV, claim(s) 46, drawn to a method for the purification of cells using a membrane vesicle according to claim 12 of Group III.

Group XXXVI, claim(s) 46, drawn to a method for the purification of cells using a membrane vesicle according to claim 16 of Group IV.

The inventions listed as Groups I-XXXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claim 1, drawn to a membrane vesicle that comprises a recombinant molecule of the human major Histocompatibility complex, does not provide a technical feature that is distinguished over the prior art, as evidenced by WO 97 05900. WO 97 05900 teaches exosomes comprising MHC Class II and membranes which contain synthetically prepared MHC Class I and II molecules, see entire patent, especially pages 5 and 6. Therefore, the instant invention lacks Unity of Invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

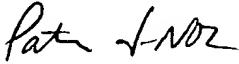
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, PhD  
Patent Examiner,  
September 8, 2002

  
Patrick J. Nolan, Ph.D.  
Primary Patent Examiner,